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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No. : 10/675,611 Confirmation No. 6361  
Appellant : William J. Boyle et al.  
Filed : September 29, 2003  
Title : EMBOLIC FILTERING DEVICES  
Art Unit : 3738  
Examiner : Christopher D. Prone  
  
Docket No.: : ACSES-63641 (G3386USP1)  
Customer No. : 24201 July 16, 2009

MAIL STOP APPEAL BRIEF-PATENTS  
Commissioner for Patents

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Dear Sirs:

**I. INTRODUCTION**

The present invention relates generally to filtering devices and systems used, for example, when an interventional procedure is being performed in a stenosed or occluded region of a body vessel to capture embolic material that may be created and released into the body fluid during the procedure. The present invention is more particularly directed to an embolic filtering system using special guide wire torque devices that facilitate the rapid removal of a peel-away delivery sheath used to position the filtering device within the patient's vasculature.

**II. NOTICE OF APPEAL**

A Notice of Appeal from the final Office Action dated April 21, 2009 is being filed concurrently herewith along with the appropriate fee.

### **III. ISSUES ON APPEAL**

At issue is whether claims 1, 2, 4, 7-10 and 12-26 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,152,946 to Broome et al. (the "Broome patent") in view of U.S. Patent No. 5,161,534 to Berthiaume (the Berthiaume patent") and in further view of U.S. Patent No. 3,459,184 to Ring (the "Ring patent").

A copy of the pending claims is attached as Exhibit A. A copy of the drawings from the application is attached as Exhibit B. A copy of the final Office Action dated April 21, 2009 is attached as Exhibit C. The Broome patent is attached as Exhibit D. The Berthiaume patent is attached as Exhibit E. The Ring patent is attached as Exhibit F.

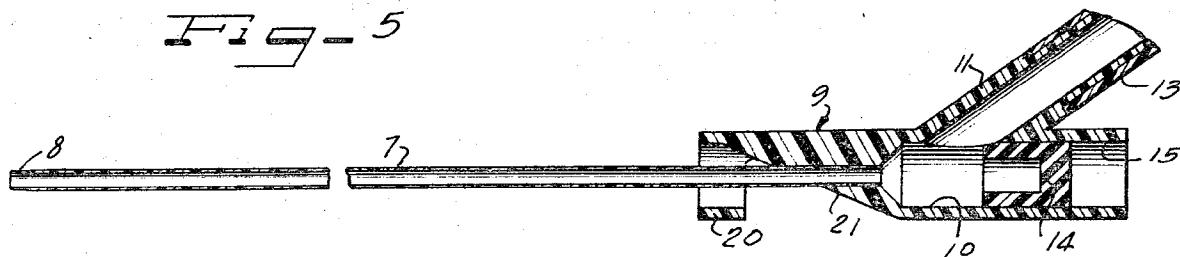
### **IV. ARGUMENT**

#### **A. Rejection of the Claims Based on the Broome, Berthiaume and Ring Patents**

All of the pending claims 1, 2, 4, 7-10 and 12-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent in view of the Berthiaume patent and in further view of the Ring patent. First, it is noted that the Ring patent is directed to an intravenous catheter placement unit which utilizes a solid needle 1 to implant a plastic catheter 7 into a patient. The Examiner has taken the position that this plastic catheter 7 constitutes a guide wire, as the term guide wire is used in the art, since "any member that can be used to track a catheter or tube to a desired site can be considered a guidewire." (page 4 of the final Office Action) The Examiner has also taken the position that the Ring device discloses a side port adapted to receive the proximal end of the sheath. Appellant strongly disagrees with each of the Examiner's positions.

Initially, it is noted that the Ring device lacks a side port for receiving the sheath. The Examiner identifies an alleged sideport near reference numeral 21 in the drawing of the Ring patent. However, this structure is not a separate sideport, but rather, is merely the

space formed between the loop 20 and the main body of the tubular fitting 9. Figure 5 of the Ring patent, reproduced below, shows the space which extends proximally from the



loop 20 to the main body of the fitting 9. There simply is no separate side port that receives the sheath. Appellant acknowledges that the inclined surface 21 does cause the sheath 18 to bend away from the catheter 7 and needle 1 during usage; however, a separate side port is not present. For this reason alone, the Ring patent fails to disclose the structure recited in the pending claims.

In the context of the present invention, the term "guide wire" is properly construed to mean a flexible elongate wire that can be used in combination with a number of medical devices, such as balloon catheters, atherectomy devices, filtering devices, just to name a few. The guide wire is generally used with the medical device to allow the device to be tracked along the wire from its free proximal end towards its distal end position within the patient's body, such that the guide wire acts as a "rail" or guide for the positioning of the device. This construction of the term "guide wire" is consistent with the meaning understood by those skilled in the art. In general, guide wires are used to find and secure a pathway through a patient's artery and the stenotic lesion. The guide wire allows the subsequent passage of therapeutic devices thereover once the guide wire has been advanced into the artery of interest.

Appellant submits that the Ring patent fails to disclose a guide wire as the term is known to one skilled in the art. The Examiner has identified the plastic catheter 7 disclosed in the ring patent as a "guide wire." Appellant submits that this catheter 7 is not

a guide wire and does not function as a guide wire as this term is known in the medical field. The Examiner maintains that it indeed functions as a guide wire. However, it is simply a plastic tubing insertable into the patient for administering fluids. The construction of the unit shown in the Ring patent, as shown above in Figure 5, actually prevents the catheter 7 from being used as guide wire. As can be seen in Figure 5, the proximal end of the catheter 7 is fixedly attached to the tubular fitting 9. Therefore, it would be impossible to use this catheter 7 as a "guide wire," as suggested by the Examiner, due to the presence of this fixing 9. This fitting at the proximal end of the catheter 7 would simply prevent one from using the catheter 7 as a guide wire. Additionally, this soft plastic catheter 7 would be incapable, by itself, of causing the sheath 18 to shear. Rather, it is the stiff metal needle 1 in the Ring device which causes the splitting of the sheath 18. Simply put, the Ring patent fails to disclose a guide wire as the term is known to one skilled in the art.

There also appears to be no motivation for one skilled in the art in placing the Ring sheath splitter on the Berthiaume torque device as suggested by the Examiner. Appellant only agrees with the Examiner's position that the Berthiaume torque device could be used on the embolic filter device disclosed in the Broome patent. In view of these apparent differences between the Ring device and the devices disclosed in the Broome and Berthiaume patents, Appellant believes that the Examiner has merely used the present claims as a road map and has selectively chosen unrelated components in prior art references in an attempt to recreate the structure defined in the pending claims. Additionally, the combinations of prior art suggested by the Examiner fail to justify why one skilled in the art would be motivated to combine them in the first place. For these reasons alone, the obviousness rejections of the pending claims should be withdrawn.

## **V. CONCLUSION**

Appellant respectfully requests that the obviousness rejections based on the combination of the Broome, Berthiaume and Ring patents be withdrawn. The combination of these references fails to create the basic structure recited in all of the

pending claims. Accordingly, all of the pending claims have been incorrectly rejected by the Examiner.

The commissioner is authorized to charge any deficiencies in fees or credit any overpayments to our Deposit Account No. 06-2425.

Respectfully submitted,

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